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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,863	10/30/2003	David E. Clapham	110313.135US3	1595

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WILMERHALE/BOSTON
60 STATE STREET
BOSTON, MA 02109

EXAMINER
WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
08/05/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

michael.mathewson@wilmerhale.com
teresa.carvalho@wilmerhale.com
sharon.matthews@wilmerhale.com

Office Action Summary	Application No.	Applicant(s)	
	10/697,863	CLAPHAM ET AL.	
	Examiner	Art Unit	
	SANDRA WEGERT	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/30/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6 and 8-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,3-6 and 8-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Status of Application, Amendments, and/or Claims

The Amendment and Remarks, submitted 30 April 2008, have been entered. Claims 4, 8, 10-12, 15, 16 and 19-22 have been amended. Claims 2, 7 and 26-111 have been cancelled (30 October 2007).

Claims 1, 3-6 and 8-25 are under examination in the Instant Application.

Withdrawn Objections/Rejections

The objection to Claims 4, 8, 10 and 11 for reciting non-elected subject matter is *withdrawn*. Applicants amended the claims to remove references to SEQ ID NO: 3 and 4 (30 April 2008).

Maintained/New Objections and/or Rejections

35 U.S.C. § 101/112, first paragraph-, Lack of Utility, Enablement.

The following is a quotation of 35 U.S.C. 101:

> **Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in**

the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-6 and 8-25 are rejected under 35 U.S.C. 101, as lacking utility. The reasons for this rejection under *35 U.S.C. § 101* are set forth at pp. 3-9 of the previous Office Action (30 May 2008). Claims 1, 3-6 and 8-25 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth in the previous Office Action (30 May 2008), one skilled in the art clearly would not know how to use the claimed invention.

As discussed in the previous Office Action (p. 3), no well-established utility exists for newly-isolated complex biological molecules. The specification does not discuss evidence or disclose experiments that impart *any* function for the claimed polynucleotide of SEQ ID NO: 1 in the context of the cell or organism. Applicants suggest that the claimed polynucleotide is a "Catsper" calcium channel similar to the disclosed mouse Catsper1 channel of SEQ ID NO: 3 and that:

"Inhibition of the activity of CatSperl causes a substantial decrease in the motility of sperm cells .... Therefore, inhibitors of the activity of the CatSperl protein can prevent penetration of the ZP [zona pellucida] and can be used as male contraceptives in men or women to cause temporary, reversible infertility."

(Remarks, p. 7, 30 April 2008).

The specification presents data in which the mouse Catsper1 channel of SEQ ID NO: 3 was tested in several assays of sperm motility and function (see Figure 4, for example). The Catsper channel of SEQ ID NO: 3 appears to be necessary for the proper functioning of mouse sperm. Such data have *not* been collected for the claimed nucleic acid of SEQ ID NO: 1 or the

polypeptide encoded by SEQ ID NO: 1. In fact with its low homology to the CATSPER family of genes (31% homology at best), it cannot be determined if the claimed nucleic acid actually even encodes a calcium channel. Furthermore even if it were a calcium channel, members of this large family of channels share several recognizable structural similarities, yet have diverse functions, as discussed in the previous Office Action (30 October 2007, p. 6). The specification does not disclose characteristics specific to a voltage-gated channel or to a calcium channel or to a member of the Catsper genus of calcium channels. Determination of any of these would require significant further research. Since the asserted utility is not available as a real world use, and significant further research beyond the disclosure is required, the asserted utility is not substantial.

Likewise, Claims 1, 3-6 and 8-25 are also rejected under 35 U.S.C. 112, first paragraph, for the reasons given in the previous Office Action (p. 7). Since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicants submit that this rejection should be withdrawn for the same reasons as stated with respect to the rejection under 35 U.S.C. § 101 (Remarks, p. 7). However, as is the case when discussing Utility of the claimed invention, the skilled artisan is not provided with sufficient guidance to use the claimed polynucleotide (SEQ ID NO: 1) for any purpose. Because a function for SEQ ID NO: 1 has not been demonstrated, the invention is not enabled.

Proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation necessary to determine the function of the nucleic acid of

SEQ ID NO: 1, the lack of direction/guidance presented in the specification regarding the same, the complete absence of working examples directed to the same, the complex nature of the invention, and the unpredictability of predicting the function of new nucleic acids based entirely on sequence, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Furthermore, as discussed in the previous Office Action (p. 8) applicants are not enabled for *fragments* or *variants* of polynucleotides: 1) at least 10-18 consecutive bases long, 2) identified by substructures of the encoded protein (such as the transmembrane domain), 3) having at least 80% sequence identity, or 4) that hybridize to the claimed nucleic acid at low or moderate stringency, as recited in Claims 1, 3-6, 8, 10 and 11. Applicants have neither made fragments of SEQ ID NO: 1, nor confirmed their function. Even if there were a patentable use for the claimed full-length polynucleotide (SEQ ID NO: 1), the claimed variants would not be enabled because the specification has not taught one of ordinary skill in the art how to use them.

Claim Rejections - 35 USC § 112, first paragraph-Written Description

The rejection of Claims 1, 3-6, 8, 10 and 11 under 35 U.S.C. 112, first paragraph- written description- is *maintained.* The reasons for this rejection based on fragments and variants of SEQ ID NO: 1 were set forth at pages 9-11 of the previous Office Action (30 October 2007). Applicants amended claims to remove reference to specific fragments of the nucleic acid encoding SEQ ID NO: 2 (such as "residues 2-40"), but did not amend claims referring to non-specific fragments, such as "at least 10 consecutive nucleotides." Applicants also did not cancel

language referring to variants identified by substructures of the encoded protein (such as the transmembrane domain), variants having at least "80% sequence identity," or nucleic acids that hybridize to the claimed nucleic acid at moderate stringency (although it is noted that claim 10 was amended from 1.0 SSC to read 0.1 SSC, which does make the stringency somewhat higher). Applicants have neither made nor used any variants of SEQ ID NO: 1 or its encoded polypeptide. Since there was no reduction to practice to support the claim language, applicants were therefore not in possession of all or a significant number of variants of SEQ ID NO: 1 which *retain the function* of SEQ ID NO: 1.

Applicants maintain that:

"it is difficult to understand how one could be in possession of the entire sequence [of SEQ ID NO: 1] and yet not in possession of the subsequences" (Remarks, p. 9).

However, as discussed in the previous Office Action (30 October 2007) adequate written description requires more than a mere statement that a fragment or variant is part of the invention and that one of skill in the art could easily make such fragments and variants. There must be a reduction to practice to support the claimed genus, specifically that of a Catsper calcium channel. Applicants made no variant polynucleotides, and as recited in the current Written Description Guidelines, Applicants must have invented the subject matter that is claimed and must be in "possession" of the claimed genus (Federal Register, 2001, Vol. 66, No. 4, pages 1099-1111, esp. page 1104, 3rd column).

To fulfill the written description requirement, a patent specification must describe an invention in sufficient detail such that one skilled in the art could clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565,

1572, 41 U.S.P.Q.2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 U.S.P.Q.2d at 1966. However, Applicants have not described or shown possession of a commensurate number of species of compounds that are 80% homologous to Catsper1 or are variants of Catsper1. Alternatively, the applicants could have described and used a representative number of species to demonstrate that they are in possession of a genus of Catsper1 variants that function in the same way as SEQ ID NO: 1. However, not only have they not demonstrated a function for the entire sequence, but they have not demonstrated that they can make functional fragments and variants belonging to the Catsper1 genus.

Claim Rejections- 35 USC § 102

The following are quotations of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of Claims 8, 10, and 12 under 35 U.S.C. 102(b), is *maintained*. This rejection was made previously because the claims embrace very short sequences of complimentary sequences which bind "at least *a portion* of SEQ ID NO: 1," as well as bind using hybridization steps that are not stringent (i.e., washing at 65°C). The rejection was made over the sequence shown in: Sanger Centre (1998, Science, 282: 2012-2018, Accession No. Z82256.1, of record). The Sanger Centre Consortium disclosed a polynucleotide sequence encoding a nematode sodium channel which is 29% identical to SEQ ID NO: 1 in the instant application. There are several short identical areas where the nucleotides are the same, such as in the region of residues 174-181. This reference meets the limitations of claims 8, 10, and 12 because "a portion" of SEQ ID NO: 1 can be a very short segment, even just one or a few bases. Applicants amended claims 8 and 10 to recite a hybridization wash step that used 0.1X SSC, rather than 1.0X SSC, but that still means that hybridization conditions are moderate (because of the 65°C rinse temperature) and the fact that the claims still recite binding to "a portion" of SEQ ID NO: 1.

Conclusion

Claims 1, 3-6, 8, 10 and 11 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Manjunath Rao, can be reached at (571) 272-0939.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

/SLW/
22 July 2008

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646